

REMARKS

1. Interview

Examiner Ponnaluri is greatly thanked for her time, comments, and courtesy during the interview held on Wednesday, July 3, 2002.

2. Status of the Claims

Claims 1-4, 6, 7, 9, 10, 17-27, 29, 33-57 and 61-64 were pending at issuance of the Restriction Requirement as correctly reflected by the Office Action Summary.

Claims 1-4, 6, 7, 9, 10, 17-27, 29, 33-57 and 61-64 have been canceled by the instant amendment without prejudice or disclaimer. Applicants reserve the right to file a divisional or continuation application on any of the subject matter canceled by way of the amendment.

By the instant amendment, Applicants introduce new claims 65-94. Applicants note at the outset that many of these claims are duplicates of the previous claims and are being introduced as "new claims" merely in an effort to provide the Examiner with a clean set of consecutively numbered claims.

3. Support for the New Claims

Support for new claims 65-94 can be found *at least* as follows:

<u>New Claim</u>	<u>Specification Support Therefor</u>
65	at least in canceled claims 1-3 and at least in Examples 4 and 6.
66	at least in canceled claim 1.
67	at least in canceled claims 1 and 2.
68	at least in canceled claims 1 and 3.
69	at least in canceled claim 10.
70	at least canceled claim 9.
71	at least canceled claim 9.

<u>New Claim</u>	<u>Specification Support Therefor</u>
72	at least canceled claim 10.
73	at least canceled claims 19 and 20.
74	at least canceled claim 21.
75	at least canceled claims 18 and 20.
76	at least canceled claim 35.
77	at least canceled claims 36 and 37.
78	at least canceled claim 22.
79	at least canceled claim 23.
80	at least canceled claim 25.
81	at least canceled claim 26.
82	at least canceled claim 27.
83	at least canceled claim 29.
84	at least canceled claim 39.
85	at least canceled claim 38.
86	at least canceled claim 43.
87	at least canceled claim 44.
88	at least canceled claim 49.
89	at least canceled claim 45.
90	at least canceled claim 46.
91	at least in canceled claims 46 and 48.
92	at least in canceled claim 50.
93	at least in canceled claim 51.
94	at least in canceled claims 52 and 53.
95	at least in canceled claim 54.
96	at least in canceled claim 55.

New Claim Specification Support Therefor

97 at least in canceled claim 55.

4. Traversal of the Restriction Requirement/Election of Species

As discussed during the course of the interview held July 3, 2002, Applicants believe that many of the categories defined in the election requirement are largely mooted by the new set of claims. Where a category may still be applicable, Applicants have designated an elected species below **with traverse**.

M.P.E.P. § 803 states that an application may be properly restricted to one or more claimed inventions only if 1) the inventions are independent or distinct as claimed, and 2) there is a serious burden on the Examiner if the restriction is not required. Thus, even if appropriate reasons exist for requiring restriction, such a restriction should not be made unless there is an undue burden on the Examiner to examine all of the claims in a single application. Applicants respectfully assert that in view of the new claims no species elections are warranted. Specifically, for a restriction requirement under M.P.E.P. § 816 an explanation of species distinction and their mutual-exclusivity (see M.P.E.P. § 806.04(f)) must be provided along with an explanation of why the burden is undue. With reference to both the now canceled claims and the newly introduced claims, no showing has been made as required by the M.P.E.P.

Applicants further submit that under M.P.E.P. § 804(f), claims restricted to different species must be mutually exclusive. The present generic claim is a method claim which recites steps which are employed with all of species, therefore, they are not mutually ~~exclusive, as discussed with the traversal of each of the individual species categories~~ below.

Applicants hereby elect, **with traverse**, the following species:

a) *target* - As the new claims no longer recites a "target", Applicants submit that the election is mooted.

b) *target structures*- Applicants elect, with traverse, a receptor. However, as discussed during the interview, the presently claimed invention is basically a *screening process* to identify antibodies from a library of antibodies those antibodies which bind undefined targets in one tissue but not another tissue. Therefore, Applicants believe that the target structure cannot be defined *a priori* for the screening. Moreover, all of the steps of the presently claimed method are performed regardless of the target structure and thus are not mutually exclusive. Therefore, the Examiner's search burden is not reduced by requiring this species election. Accordingly, Applicants submit that this category should be eliminated in view of the at least new claims and above arguments.

c) *physiological process* - Applicants elect, with traverse, a pathological process. However, Applicants submit that the presently claimed invention is directed to a *method* of identifying antibodies against a target structure. The steps employed in identifying target structures of a pathological process versus a developmental process are the same and thus are not mutually exclusive. Accordingly, no additional burden falls upon the Examiner to search the new claims. Therefore, Applicants submit that they should not be limited to one physiological process and that this category be eliminated in view of the at least new claims and above arguments.

d) *species of pathological process* - Applicants elect, with traverse, inflammation. Here, as in c) above, the steps required to practice the method of the presently claimed invention for a particular species of pathological process versus another do not vary and are not mutually exclusive. Accordingly, no additional burden falls

upon the Examiner to search the claims nor would this species election alleviate the perceived burden. Thus, Applicants submit that this category should be eliminated in view of the at least new claims and above arguments.

e) location of the target structure - Applicants elect, with traverse, extracellular. However, as in b) above, the presently claimed invention is basically a screening method wherein the target structure is not predefined. Moreover, the presently claimed method recites the use of tissue sections which necessarily expose more than one category of target structure location, *i.e.*, extracellular, intracellular, intranuclear, and cell surface antigens are simultaneously exposed. The steps employed in the method are not dependent upon the location of the target structure and thus are not mutually exclusive. Thus, Applicants should not be limited to one particular target structure location. Accordingly, this category should be eliminated in view of the at least new claims and above arguments.

~~*f) tissue type* - Applicants elect, with traverse, bone marrow. However, the presently claimed invention is directed to a *method* of identifying antibodies which employs the same steps regardless of which tissue is used. Thus, the Examiner again does not reduce the perceived search burden by requiring election of one particular tissue. The elegance of the presently claimed method allows it to be practiced on any tissue from which a section can be made. Accordingly, Applicants believe this category should be eliminated in view of the at least new claims and above arguments.~~

g) type of initial library - Applicants elect, with traverse, a combinatorial library. However, this library is merely a starting reagent - any antibody library can be employed. The method steps utilizing any such library are the same and the same search is required regardless of type of initial library. The claimed method centers

on the use of the selection process, not the initial library. Electing a particular species here adds another layer of unnecessary complexity which adds to the search burden, it does not ease it. Accordingly, this category should be eliminated in view of the at least new claims and above arguments.

h) method of production of combinatorial library - Applicants elect, with traverse, immunization. However, the method of production of the initial library is irrelevant to the steps employed in the claimed method of identifying antibodies which bind to one tissue and not another. The search burden is not reduced by adding another layer of complexity to the search which does not control the method. Accordingly, this category should be eliminated in view of the at least new claims and above arguments.

i) amplifying step - Applicants elect, with traverse, PCR. However, the choice of procedure for this step is merely technical and not critical to the claimed method.

~~The procedure used depends mainly on convenience and the initial library used~~
(*e.g.*, phage). Applicants further point out that one cannot separate the PCR method from the use of bacterial cells. Accordingly, Applicants believe this category should be eliminated in view of the at least new claims and above arguments.

j) genetic information - This language no longer appears in the new set of claims and is thus mooted. Hence, Applicants cannot elect a species.

k) method of acquiring - The dependent claim describing the various species (identifying, producing, characterizing, selecting, enriching, defining) in this category has been eliminated from the new set of claims and is thus mooted. Hence, Applicants cannot elect a species.

l) target structure displayed - The dependent claim describing the various species (authentic cellular epitope, phenotypic epitope) in this category has been eliminated from the new set of claims and is thus mooted. Hence, Applicants cannot elect a species.

m) cleavage site - Applicants elect, with traverse, proteolytic. However, the steps of the presently claimed method using an alternative means of cleavage are not mutually exclusive. The release of the binding structures can be achieved by enzymatic means among many other methods. Therefore, Applicants submit that this category should be eliminated in view of the at least new claims and above arguments.

n) protease - Applicants elect, with traverse, blood clotting factor Xa. However, the type of protease used does not affect the steps of the presently claimed method. Any protease which can cause cleavage of the bound element, leaving the monoclonal antibody or fragment-attached-to-the-tissue, can be used and thus, the protease is not considered to be limiting of the invention. As stated above, an election of species therefore cannot alleviate the perceived burden of searching either the canceled or new claims. Accordingly, in view of the new claims and the above arguments Applicants submit the category should be eliminated.

Thus, for at least all of the reasons set forth above, withdrawal of the requirement for election of species is requested and believed to be in order. Further and favorable consideration of all the claims of record on the merits is respectfully requested.

CONCLUSION

The foregoing amendments are being made to place the application in better condition for examination. A favorable action on the merits is respectfully solicited.

If there are any other fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 02-4800. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for in the attached extension of time request, such an extension is requested and the fee should also be charged to our Deposit Account.

In the event that the Examiner has any outstanding issues, she is invited to contact the undersigned attorney at her convenience.

Respectfully submitted,
BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: 

Mercedes K. Meyer
Registration No. 44,989

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

Date: July 12, 2002